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09/453,801	12/03/1999	Saswati Chatterjee	1954-287	3067

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EXAMINER	
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ART UNIT	PAPER NUMBER
1636	22

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/453,801	CHATTERJEE ET AL.
	Examiner	Art Unit
	Gerald G Leffers Jr., PhD	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-10,13-15,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-10,13-15,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 9/25/03 as Paper No. 21, in which several claims were cancelled (claims 19-21) and in which several claims were amended (claims 1, 8-10). In addition, the specification was amended in the Brief Description of the Drawings to specifically refer to different panels in the figures, and to include specific information regarding particular cytokine levels required to practice the claimed invention.

Claims 1-5, 8-10, 13-15, 17-18 and 22-23 are pending in the instant application. Any rejection of record in the previous office action not addressed herein is hereby withdrawn. This action is FINAL.

Response to Amendment/Arguments

Applicants' amendment submitted in Paper No. 21 introduces impermissible NEW MATTER into the specification (i.e. at page 14, lines 9-23) and into the claims (i.e. "...wherein the levels of said cytokines are no greater than...1.5 ng/ml stem cell factor..."). Applicants' response asserts that this amendment of the claims and specification to indicate that one practices the claimed invention where the level of stem cell factor (SCF), rather than granulocyte macrophage colony stimulating factor (GMCSF) is made to correct an "obvious error". The response asserts: **1)** it has only recently come to applicants' attention that the specification and claims erroneously teach that the wrong term (granulocyte macrophage colony stimulating factor or "GMCSF") was used in place of the term "stem cell factor" or "SCF", **2)** the amendments are supported in the specification at page 38 (lines 25-33 in Example 3; culture conditions including 1 ng/ml SCF not GMCSF), **3)** at pages 20-21 the specification discusses examining

CD34+++/CD38- cells in media containing IL-3, IL-6 and SCF residing in G0 for cell division to confirm the non-dividing quiescent status of the transduced cells, **4)** the provisional application (i.e. 60/111,017) to which instant application claims benefit refers to increasing concentrations of IL-3, IL-6 and stem cell factor for study of metaphases after transduction (e.g. page 28, lines 15-19), **5)** the provision application also discusses low and high concentrations of SCF for culture of transduced cells and FISH methods (e.g. pages 46 and 53), as well as low concentrations for maintaining the transduced stem cells during mitotic quiescence testing (e.g. page 56, lines 9-11), **6)** the provisional application clearly refers to methods that use a combination of IL-3, IL-6 and SCF for the inventive methods (e.g. long term culture initiating cell assays wherein granulocyte-macrophage colony stimulating factor was in high concentration-50 ng/ml; page 45-line 24), **7)** the provisional application teachings culturing of primary CD34 cells in media that included high concentrations of GMCSF (~1 mg/ml), **8)** the latter culture methods taught in the provisional application were clearly not intended to describe the inventive method of the instant specification and would readily be recognized as unrelated to the transduction methods claimed here, **9)** the skilled artisan would necessarily recognize from the priority document that the granulocyte-macrophage colony stimulating factor is not useful for the inventive transduction methods, but that the stem cell factor is useful, **10)** the prior art recognized that culturing cells in IL-3, IL-6 and GMCSF in the absence of CSF would not have maintained the cells as mitotically dormant, quiescent hematopoietic stem cells in G0, **11)** the prior art recognized that the presence of stem cell factor was necessary to maintain the stem cells, **12)** the inadvertent usage of GMCSF rather than SCF in the specification and claims is an obvious error under the standards of MPEP 2163.07(II), the correction of which is supported by the instant specification, and **13)** the

rectification of which is obvious due to the teachings of the instant specification (e.g. the working examples where SCF is used explicitly with IL-3 & IL-6)

Applicants' arguments concerning the instant specification are not considered persuasive. First, the nature of the limitation that is at issue is that the concentration of the critical cytokine (GMCSF or SCF) is at a level of "no more than 1.5 ng/ml" so that the hematopoietic stem cells are maintain in a G0 cell cycle state. The fact that the working examples of the instant application may not explicitly state that the culture media used in those examples did not comprise GMCSF does not support a contention that one would recognize that the presence of GMCSF at concentrations higher than 1.5 ng/ml would not be inhibitory to maintaining the cells at G0. Similarly, the observation that SCF is present at 1 ng/ml in the media used in the working examples merely indicates that the presence of SCF is critical to practicing the claimed invention. This observation has already been taken into account by the examiner in making the scope of enablement rejection of record (see below). The observation that SCF is present at 1 ng/ml in the working examples merely provides support for the presence of SCF in the culture media at that specific concentration and does not in any way provide support for indicating that the concentration needs be kept below 1.5 ng/ml, or that SCF is present at any other concentration. Other concentrations, or concentration ranges for SCF, are not supported in the instant specification under 112 1st for description purposes. It is further noted that the specification indicates that the working examples were done with media comprising 1 ng/ml GMCSF (i.e. page 16, line 17).

With regard to arguments directed to the priority application, these arguments are not persuasive. First, it is noted that while the instant application claims benefit of the earlier

application, it does not incorporate its teachings by reference. Therefore, the teachings of the provisional application cannot considered as providing literal or inherent support for the amendment. Moreover, there does not appear to be an equivalent teaching in the provisional application concerning the maximum levels of each of the cytokines/growth factors that can be present in order to maintain the cells in a quiescent, G0 state (i.e. at levels of no greater than about 15 ng/ml IL-3, 15 ng/ml IL-6 and 1.5 ng/ml GMCSF and/or SCF). With regard to the cited passages from the provisional application, it is not clear how well the cited experiments correspond to the working examples presented in the instant application wherein IL-3, IL-6 and SCF are maintained at specific concentrations so that hematopoietic stem cells are maintained at G0 and transduced with an AAV vector.

The assertions concerning the state of the prior art are interesting. It is asserted that it was known at the time of the filing that culturing cells in IL-3, IL-6 and GMCSF (e.g. including levels of 15 ng/ml IL-3 and IL-6, and 1.5 ng/ml GMCSF) would not maintain stem cells as mitotically dormant and that the presence of SCF is necessary to do so. First, this assertion implies that applicants are aware of some prior art reference or combination of prior art references that would either anticipate or make obvious the claimed invention. Applicants are invited to provide such references for the record. Second, the response at this point appears to be citing a Declaration provided by Dr. Chaterjee, an inventor for the instant invention, where she describes the teachings of Zhou et al as comprising levels of IL-3 and GMCSF that are ten times those taught in the instant specification and which would, as taught by the instant specification, necessarily result in mitosis (i.e. loss of G0 cell cycle status; see Paper No. 10, page 7). This

statement by Dr. Chaterjee, made as late as 1/3/2002 appears to support the concept that maintaining low levels of GMCSF is a critical element of the claimed invention.

M.P.E.P 2163.07(II) states:

II. OBVIOUS ERRORS

An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. In re Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).

Where a * foreign priority document under 35 U.S.C. 119 is of record in the >U.S.< application file, applicant may not rely on the disclosure of that document to support correction of an error in the pending >U.S.< application. Ex parte Bondiou, 132 USPQ 356 (Bd. App. 1961). This prohibition applies regardless of the language of the foreign priority documents because a claim for priority is simply a claim for the benefit of an earlier filing date for subject matter that is common to two or more applications, and does not serve to incorporate the content of the priority document in the application in which the claim for priority is made. This prohibition does not apply ** where the *>U.S.< application explicitly incorporates **>the foreign priority< document by reference. >Where a U.S. application as originally filed was in a non-English language and an English translation thereof was subsequently submitted pursuant to 37 CFR 1.52(d), if there is an error in the English translation, applicant may rely on the disclosure of the originally filed non-English language U.S. application to support correction of an error in the English translation document.<

2163.07(a) Inherent Function, Theory, or Advantage

By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. In re Reynolds, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); In re Smythe, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973). "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

2163.07(b) [R-1] Incorporation by Reference

Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter. See MPEP § 608.01(p) for Office policy regarding incorporation by reference. >See MPEP § 2181 for the impact of incorporation by reference on the determination of whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph when 35 U.S.C. 112, sixth paragraph is invoked.<

For the reasons outlined above, the skilled artisan would not necessarily recognize that inclusion of the limitation "...cytokine levels of no greater than about...1.5 ng/ml granulocyte macrophage colony stimulating factor..." in the originally filed specification was an obvious error and that the obvious resolution would be to substitute the term "stem cell factor" or "SCF" for "granulocyte macrophage colony stimulating factor" or "GMCSF". For these reasons, the following objection to the specification, and rejection of the instant claims, for incorporation of NEW MATTER are made in this office action.

Specification

The amendment filed 9/25/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: replacement of the terms "granulocyte macrophage colony stimulating factor" or "GMCSF" with the term "stem cell factor" on page 14, lines 19-23. There is no literal or inherent support in the specification as filed for this limitation. Nor is the limitation an "obvious error" for the reasons indicated above.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 8-10, 13-15, 17-18 and 22-23 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection, necessitated by applicants' amendment of the claims in Paper No. 21**.

Each of the rejected claims comprises a newly added limitation reciting specific levels of stem cell factor (i.e. SCF) and deletion of any reference to particular levels of granulocyte macrophage colony stimulating factor (i.e. GMCSF). There is no literal or inherent support for these limitations in the originally filed claims and specification. Nor are these changes due to an "obvious error" such that there is support in the originally filed specification for the amendments to the claims (see the arguments presented in Response to Amendment section above). Therefore, the limitations are impermissible NEW MATTER.

Claims 1-5, 8-10, 13-15, 17-18 and 22-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for embodiments wherein the hematopoietic cells in the G0 phase of the cell cycle are maintained under conditions where IL-3, IL-6 and cell stimulating factor (CSF) are present, and where cytokine levels are no greater than about 15 ng/ml IL-3, 15 ng/ml IL-6 and 1.5 ng/ml of granulocyte-macrophage colony stimulating factor (GMCSF), does not reasonably provide enablement for embodiments where IL-3, IL-6 and CSF are not present, or where IL-3, IL-6 and GMCSF are at higher than the cited levels. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to practice the invention commensurate in scope with these claims. **This rejection is maintained for reasons of record in Paper No. 19, mailed 12/18/02 and repeated below.**

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The nature of the invention is extraordinarily complex, involving the difficult purification of hematopoietic stem cells (e.g. $CD34^{+++}$ $CD38^{-}$ cells) that are in the G0 phase of the cell cycle and maintaining/transducing the cells in such a manner that the cells remain in the G0 phase of the cell cycle, and wherein the transferred DNA remains stably integrated into the genome of the hematopoietic stem cells for at least 4 weeks.

Breadth of the claims: The claimed methods are very specific in that the methods are necessarily performed on hematopoietic stem cells that are in the G0 phase of the cell cycle. However, the claims are broadly drawn with regard to the cell culture conditions required to maintain the hematopoietic stem cells in the G0 cell-cycle state.

Guidance of the specification: The specification teaches that there are essentially two main critical elements of the claimed methods: 1) purification of the extremely rare hematopoietic stem cells that are in the general cell population and are in the G0 phase of the cell cycle, and 2) maintaining the cells such that the purified hematopoietic stem cells remain in the G0 phase of the cell cycle at least during transduction.

With regard to the first element, the applicants utilized a 3-step approach to isolating a sufficiently large number of purified hematopoietic stem cells in G0 for transduction to have a reasonable chance of success. This 3-step approach involved initial purification of $CD34^+$ cells from mononuclear cells with Multineyi columns, followed by flow sorting of the $CD34^+$ population based upon DNA and RNA content to segregate out only those $CD34^+$ cells which were in the G0 phase, and finally, sorting of the resulting cell population to obtain those cells which were $CD34^+$ and $CD38^-$ (e.g. pages 16-17 of the instant specification; Chatterjee 1.132 Declaration, paragraph 6). The specification teaches that other suitable methods are known in the art for obtaining sufficient numbers of purified hematopoietic stem cells at G0 for transfection (e.g. page 17, line 11 of the instant specification).

With regard to the conditions for maintaining the cells in the G0 state, the specification teaches that under the conditions of the methods of the invention, with particular regard for low cytokine levels, the hematopoietic stem cells in culture remain quiescent for up to 2 days. The specification teaches that in order to perform the method, low levels of the cytokines IL-6, IL-3 and GMCSF are important and that the higher the cytokine levels, the more the cells are stimulated to undergo mitosis. Alternatively, the cells will die if the levels of the recited factors are too low. For these reasons, the specification teaches that it is advantageous to use cytokine levels of no greater than 15 ng/ml IL-3, 15 ng/ml IL-6, and 1.5 ng/ml of GMCSF (e.g. pages 13-14 of the instant specification). There are no teachings in the instant specification for practicing the claimed methods with culture conditions where IL-3, IL-6 and SCF are not present, or where IL-3, IL-6 and GMCSF are present at levels greater than about 15 ng/ml IL-3, 15 ng/ml IL-6 and 1.5 ng/ml GMCSF.

The existence of working examples: There are no working examples in the instant specification for practicing the claimed methods with culture conditions where IL-3, IL-6 and SCF are not present, or where IL-3, IL-6 and GMCSF are present at levels greater than about 15 ng/ml IL-3, 15 ng/ml IL-6 and 1.5 ng/ml GMCSF.

State of the art: The state of the art with regard to maintaining extremely primitive hematopoietic cells at the G0 phase of the cell cycle at the time of applicants' invention was underdeveloped. In her declaration filed under 1.132 to overcome the prior art (Paper No. 10, filed 1/17/02), Dr. Saswati Chatterjee, one of the instant inventors, states that prior to the instant invention, transduction of extremely primitive, G0, quiescent, pluripotent stem cells had not been demonstrated. Dr. Chatterjee makes clear that the levels of cytokines in the cell culture are critical to maintaining the cells at G0. For instance, Dr. Chatterjee states that the conditions taught by Zhou et al, with relatively high levels of IL-3 and GMCSF, would result in mitosis and loss of the G0 cell cycle status (page 7, paragraph 11). Alternatively, according to Dr. Chatterjee, even if the factors IL-3, IL-6 and GMCSF are present at the levels indicated in the instant specification as being within the optimal range (i.e. IL-3, 10ng/ml; IL-6, 5ng/ml and GMCSF at 1ng/ml), these factors are not art recognized as being enough to support stem cells. Dr. Chatterjee distinguishes, at least in part, the methods of the instant invention over previous work done by applicants' group, Fisher-Adams et al, based on the observation that cell stimulating factor was present in the methods of the instant specification and was critical for supporting survival of the hematopoietic stem cells (paragraph 9, Paper No. 10).

Predictability of the art: Given the teachings of the instant specification with regard to the difficulties of maintaining the hematopoietic stem cells in the G0 state without inducing

mitosis and still maintaining survival, the lack of teachings or working examples in the instant specification or prior art where hematopoietic stems cells are maintained and transduced in culture with culture conditions other than those recited above, practicing the claimed methods with cytokine levels and compositions other than those indicated above would have been unpredictable. One of skill in the are would have had to resort to unpredictable, trial-and-error experimentation in order to develop culturing/transduction conditions where IL-3, IL-6 or SCF were not present, or where cytokine levels are greater than about 15 ng/ml IL-3, 15 ng/ml IL-6 and 1.5 ng/ml of granulocyte-macrophage colony stimulating factor (GMCSF).

The amount of experimentation necessary: Based on the consideration of all of the factors outlined above, it would have required undue, unpredictable experimentation to practice the claimed methods where IL-3, IL-6 or SCF were not present, or where cytokine levels were greater than about 15 ng/ml IL-3, 15 ng/ml IL-6 and 1.5 ng/ml of GMCSF. Therefore, the instant specification is not considered enabling for the full scope of the broadly claimed invention.

Response to Arguments

Applicant's arguments filed in Paper No. 21 have been fully considered but they are not persuasive. The response filed in Paper No. 21 essentially argues that the amendment to the claims to substitute "stem cell factor" or "SCF" for the term "granulocyte macrophage colony stimulating factor" or "GMCSF" takes into consideration the grounds for the rejection and overcomes the rejection. The response further argues that the original use of the terms "granulocyte macrophage colony stimulating factor" or "GMCSF" was an "obvious error" and

that substitution of the terms "stem cell factor" or "SCF" resolves the issue and obviates the rejection.

For claim 23, this argument is not persuasive because there is no amendment made to claim 23 and no separate argument made as to why the rejection should not stand. With regard to the remainder of the rejected claims, the argument that the amendment obviates the rejection is not persuasive in that, for the reasons outlined above and incorporated here by reference, the substitution of the terms "stem cell factor" or "SCF" for the terms "granulocyte macrophage colony stimulating factor" or "GMCSF" is New Matter and does not solve and "obvious error". To summarize, there is nothing on record that provides convincing evidence, contrary to the teachings of the originally filed specification, that 1) it is not critical to maintain the concentration of GMCSF below 1.5 ng/ml in the culture media, and 2) it is critical to maintain the levels of SCF below 1.5 ng/ml so that the hematopoietic stem cells remain in G0. Therefore, the grounds for the scope of enablement rejection made above remain and the rejection is maintained for reasons of record.

Drawings

The drawings were received on 2/28/2003. These drawings have been reviewed by the Draftsperson and are acceptable.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr., PhD
GERRY LEFFERS
PRIMARY EXAMINER
Primary Examiner
Art Unit 1636

Ggl